K071040
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Wright THERAPY PRODUCTS

5. 510(K) SUMMARY

MAY 2 2 2007

§807.92 (a)(1)

Submitter's Name:	Wright Therapy Products
Address:	103-B International Drive Oakdale, PA 15071-3907
Telephone Number:	800-631-9535
Contact Person:	Carol Wright, President and CEO
Date of Summary Preparation:	February 28, 2007

§807.92 (a)(2)

Trade Name:	Wright 51 and 52 Sequential Compression System
Common Names:	Lymphedema pump Pneumatic compression pump or device Compression pump
Classification Name:	Sleeve, Limb, Compressible
Product Code:	JOW, 21 CFR 870.5800

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Devices: K961797 Wright Pro-Lite
K961292 Wright Solo

§807.92 (a)(4)

Description of Device:

The Wright 51 and 52 Sequential Compression System consists of a sequential, segmental, intermittent, pneumatic compression pump and appropriate limb appliances. It is typically used to compress an upper or lower body extremity.

The pump consists of an enclosure that contains a small air compressor, solenoid valves, printed circuit board including a programmable microprocessor, graphic display, and associated electronic circuits and pneumatic connections. Software controls the sequential opening and closing of the solenoid valves, which are connected to five (5) external pressure ports. The pressure ports are connected to the limb appliance through a hose assembly.

The inflatable limb appliance is made of fabric and may comprise from one to five cells, with the length of the appliance dependent upon the physician's order

or patients limb length. In operation, the pump fills the inflatable limb appliance with air, to prescribed, preset pressures --each cell in sequence. This simple repetition of the sequence of compression and exhaust improves return blood circulation for the patient.

§807.92 (a)(5)

Intended Use:

The Wright 51 and 52 Sequential Compression System is for treatment of lymphedema, venous insufficiencies, and other edematous conditions.

§807.92 (a)(6)

Comparison of Technical Characteristics

The Wright 51 and 52 Sequential Compression System is comparable to the previously cleared predicate devices:

- Same intended use
- Same operating principle
- Similar technology
- Same manufacturing process

In the new therapy device the pump is controlled by software in a microprocessor along with associated electronic circuits, while the predicate devices uses relay controls. The user interface of the new device is based on a touch screen and digital display, compared to analog knobs and meters in the predicate device. The new and the predicate devices use limb appliances of the same material, with the maximum number of cells increased from three to five in the new device.

§807.92 (b)(1)

Nonclinical Testing:

The evaluation of the device consisted of risk analysis to confirm that the device is as safe as the predicate devices and bench tests to verify conformity to performance specifications. Bench performance testing consisted of measurements of the sequence, timing, and pressure of therapy delivery along with verification of the functionality of the operator interface. In addition, electrical safety and electromagnetic compatibility testing to consensus standards was conducted.

§807.92 (b)(2)

Clinical Testing: None

§807.92 (b)(3)

Conclusion

Based on the above, we conclude that the Wright 51 and 52 Sequential Compression System is substantially equivalent to the legally marketed predicate device, and does not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 22 2007

Wright Therapy Products
c/o Barbara Majchrowski
Senior Project Engineer
5200 Butler Pike
Plymouth Meeting, PA 19426-1298

Re: K071040
Trade/Device Name: Wright 51 and 52 Sequential Compression System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible limb sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 11, 2007
Received: April 12, 2007

Dear Ms. Majchrowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vuchnes

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K071040

Device Name: Wright 51 and 52 Sequential Compression System

Indications For Use:

The Wright 51 and 52 Sequential Compression System is for treatment of lymphedema, venous insufficiencies, and other edematous conditions.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vedrine

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071040